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ATTORNEY DOCKET NO APPLICATION NO. FILING DATE FIRST NAMED INVENTOR J. 09/182,645 10/30/98 LI 23737 **EXAMINER** Г HM12/1114 PINO, MARK J. WANG, S SHANKS & HERBERT **ART UNIT** PAPER NUMBER 1033 N. FAIRFAX ST. 1617 SUITE 306 ALEXANDRIA VA 22314 DATE MAILED: 11/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<u> </u>			Application No.	7	Applicant(s)	
Office Action Summary		09/182,645		LI ET AL.		
		-	Examiner		Art Unit	
		Shengjun Wang		1617		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1)⊠	Responsive to communication(s) filed	on <u>11 Se</u>	eptember 2000 .			
2a)⊠	This action is FINAL. 2b) This	s action is non-final.		•	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-38</u> is/are pending in the application.						
4a) Of the above claim(s) 1-25,28-31 and 35-38 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>26, 27 and 32-34</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claims are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are objected to by the Examiner.						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. § 119						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).						
Attachment(s)						
16) 🔲 Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PT mation Disclosure Statement(s) (PTO-1449) Pap		19) 🔲 No		y (PTO-413) Paper I Patent Application (I	

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DETAILED ACTION

The receipt of Applicants' amendments and remarks submitted September 11, 2000 is acknowledged.

1. Claims 1-25, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and claims 28-31 and 35-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9 submitted on Feb. 1, 2000.

The claims have been examined insofar as they read on the elected invention and species.

Claim Rejections 35 U.S.C - 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 26,27 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanuma (AB and AC) in view of both Wielckens et al. (BQ), and Wachsman (BO) for reasons stated in the prior office action.

Response to the Arguments

Applicants amendments and remarks submitted September 11, 2000 are sufficient to overcome the disclose objection and the rejection under 35 U.S.C. § 112, second paragraph set forth in the prior office action.

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Applicants' arguments relating to the rejection under 35 U.S.C. § 103 have been fully considered, but are not persuasive for reasons stated below.

Regarding the comments that Wachsman and Wielckens do not expressly teach the employment of PARG inhibitor for treatment of disease related to activity of poly(ADP-ribose)polymer, e.g., cellular energy depletion, apoptosis, or neurological disorders, note that question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278.

Wachsman teaches that "...inhibitors of PARG would retard endonuclease activation and apoptosis." Page 30, left column, lines 11-13. Wachsman also teaches, as cited by applicants' in the response, "The steady level of poly(ADP-ribose), Is strongly influenced by the intracellular NDA concentration, as well as by the activities of poly(ADP-ribose) glycohydrolase and other enzymes involved in polymer degradation." The statement that "Little is know about the glycohydrolase, except that it is readily inactivated at 43 oC" appears to address the physical and chemical properties of the enzyme. The physiological properties of the enzyme are well known as defined by its name.

Wielckens teaches the relationship between NAD and depletion of cellular energy.

Wielckens further suggests the effect of PARG activity and NAD. Particularly, PARG may cause high turnover of poly(ADP-ribose), which consequently lead to NAD depletion. See, page 12876. Further, since poly(ADP-ribose)polymerase, (ADP-ribose)glycohydrolase and poly(ADP-ribose)glycohydrolase work in concert in the process of poly(ADP-ribose) turnover, it

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is reasonably expected that inhibiting one enzyme will downregulate the activity of the others, i.e., inhibiting poly(ADP-ribose)glycohydrolase will downregulate the activity of poly(ADP-ribose)polymerase.

Take all the references as whole, the cited references have fairly suggested the claimed invention. Nothing unobvious is seen in the claimed invention.

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 1-25 drawn to an invention nonelected with traverse in Paper No. 9 submitted February 1, 2000. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

AU 1617

November 10, 2000

RUSSEDL TRAVERS
PRIMÁRY EXAMINER
GROUP 1200